

### STATE OF CONNECTICUT

Department of Consumer Protection Drug Control Division

# Pharmacist Prescribing of Hormonal Contraceptives October 2023

#### **Background**

Public Act 23-52 allows licensed pharmacists who have completed an approved educational training program to prescribe hormonal contraceptives to patients as clinically appropriate. The Department is currently working to develop regulations and screening documents to implement the law. Once the regulations and related documents have been approved, pharmacists may begin prescribing hormonal contraceptives. The pharmacist is the prescriber of record in the event a hormonal contraceptive is prescribed. Additional information is available on the Department of Consumer Protection's Drug Control Division website at http://ct.gov/dcp/dcd.

Pharmacists who have not taken an approved training program may still prescribe hormonal contraceptives as part of a collaborative drug therapy management agreement pursuant to Connecticut General Statutes Section 20-631 as appropriate.

No additional training program is required of pharmacists dispensing hormonal contraceptives with a valid prescription written by a licensed practitioner (physician, advanced practice registered nurse, physician assistant, etc.) authorized to prescribe such medication within the scope of their professional practice.

#### **Definition**

"Hormonal contraceptive" means a drug, including, but not limited to, a hormonal contraceptive patch, an intravaginal hormonal contraceptive or an oral hormonal contraceptive, composed of a hormone, or a combination of hormones, approved by the federal Food and Drug Administration to prevent pregnancy. This does not include intrauterine devices or implants used to prevent pregnancy.

#### **General considerations**

- 1. To prescribe and dispense hormonal contraceptives:
  - a. A pharmacist must have completed a training program approved by the Department that is accredited by the Accreditation Council for Pharmacy education and that:
    - Concerns prescribing emergency contraceptives and hormonal contraceptives by a pharmacist, and,
    - ii. Addresses appropriate medical screening of patients, contraindications, drug interactions, treatment strategies and modifications and when to refer patients to medical providers.
  - b. The pharmacist has reviewed the most current version of the <u>United States Medical Eligibility</u>

<u>Criteria (USMEC) for Contraceptive Use</u> published by the Centers for Disease Control and Prevention, or any successor document.

- c. The pharmacist completes a screening document, made available on the Department of Consumer Protection's website, and such document is retained for at least three years. The pharmacist may use their professional discretion to require more frequent screenings as clinically appropriate. The screening document is being developed and will be posted on the Department's website once available.
- 2. The training program must be developed for the purpose of *prescribing* contraceptives. For example, a continuing education program that only provides education about the pharmacology of contraceptives would not be sufficient. The regulations outline the minimum criteria for the educational program.
- 3. Pharmacy technicians who have completed the training program described above may, at the pharmacist's request, assist the pharmacist in prescribing a hormonal contraceptive by:
  - a. Providing the screening document to the patient;
  - b. Taking and recording the patient's blood pressure; and,
  - c. Documenting the patient's medical history.
- 4. Upon request by a representative of the Department, pharmacists and technicians must provide proof that they have completed the required training.
- 5. Pharmacists may prescribe a contraceptive only if the intended use is for contraception.
- 6. Pharmacists who prescribe hormonal contraceptives must keep a written (written includes type-written) copy at each location where contraceptives are prescribed or dispensed. A copy of this document must be made available upon request by a representative of the Department. Each prescribing pharmacist shall ensure that they are utilizing the most current version of this form as it is subject to change.
- 7. Copies of all documents related to the prescribing of hormonal contraceptives by pharmacists will be made available on the Department's Web site at http://ct.gov/dcp/dcd.

#### <u>Procedure</u>

- 1. When an individual requests a hormonal contraceptive, the pharmacist must complete the following steps:
  - a. Determine the age of the patient:
    - i. If the patient is 18 years of age or older, the pharmacist may prescribe a contraceptive by following this document.
    - ii. If the patient is under the age of 18, the pharmacist may issue a prescription only if the pharmacist confirms that the patient has previously been prescribed a contraceptive by a licensed physician, physician assistant, or advanced practice registered nurse. The pharmacist must keep an

electronic or written record of the action taken to make this confirmation for a minimum of two years.

- a) With the patient's permission, the pharmacist may contact the office or clinic where the patient visited a healthcare provider to confirm that a prescription was issued. This can be done by telephone call, facsimile, or by accessing a health record system shared with the provider.
- b) With the patient's permission, the pharmacist may contact a pharmacy that dispensed a contraceptive prescription to the patient. This can be done by telephone call, facsimile, or by accessing a patient record system shared with the other pharmacy.
- c) The pharmacist may accept documentation or other evidence from the patient that demonstrates the patient has received a prescription for a contraceptive. (Examples, a visit summary from a clinic that indicates a prescription was issued; or a prescription package or container that bears a label with the patient's name, the name of the pharmacy that dispensed the contraceptive, date of dispensing, and the name of the prescriber).
- iii. When considering prescribing to someone under the age of 18, the pharmacist should be familiar with all applicable laws and available guidance.
- b. If the pharmacist will be prescribing a continuation of a hormonal contraceptive that the patient has previously been prescribed: Confirm that the patient has had a clinical visit with a physician, physician assistant, or advanced practice registered nurse within the previous three (3) years The pharmacist must keep an electronic or written record of the action taken to make this confirmation.
  - i. With the patient's permission, the pharmacist may contact the office or clinic where the patient visited the healthcare provider to confirm that the visit occurred. This can be done by telephone call, facsimile, or by accessing a health record system shared with the provider.
  - ii. The pharmacist may accept documentation the provider gave to the patient that confirms that a visit has occurred. (For example, a visit summary).

Without such confirmation, the pharmacist may not prescribe a refill.

c. Have the patient complete the *Connecticut Hormonal Contraceptive Self-Screening Questionnaire* found near the end of this document (in the primary spoken language of the recipient, upon request and when possible). The Questionnaire is also found on the Department's web site as a standalone document. If the patient does not complete the questionnaire, a prescription cannot be issued. The completed questionnaire should be kept on file for a minimum of three years. The patient must fill out the questionnaire at least once

- every 12 months. The Connecticut Hormonal Contraceptive Self-Screening Questionnaire may be used as the record of the prescription.
- d. Review the self-screening tool answers with the patient and clarify responses if needed.
- e. Measure and record the patient's seated blood pressure if combined hormonal contraceptives are requested or recommended.
- f. Complete the Standard Procedures Algorithm for Connecticut Pharmacists Prescribing of Contraceptives. As part of that process, the pharmacist must evaluate the health and history of the patient using the latest version of the <u>United States Medical Eligibility Criteria (USMEC) for Contraceptive Use</u> developed by the federal Centers for Disease Control and Prevention (CDC). Pharmacists may use the Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, which is color-coded to match the Connecticut Hormonal Contraceptive Self-Screening. Pharmacists may also use the Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, that was prepared by the CDC and is available on the Department's Web site.
  - i. If the evaluation indicates that a hormonal contraceptive is indicated for the patient, the pharmacist may prescribe one as outlined in this document.
  - ii. If the evaluation indicates that hormonal contraceptives are contraindicated for the patient, the pharmacist **must not** prescribe one.
  - iii. If the evaluation indicates that patients should be referred to their primary care provider or to a nearby clinic or hospital (if the patient does not have a primary care provider), the pharmacist must not issue a prescription and must make the referral. The *Pharmacist Referral and Visit Summary* template provided below may be used for this purpose.

Note: The Connecticut Hormonal Contraceptive Self-Screening Questionnaire asks about the patient's tobacco and nicotine use. While some evidence exists regarding the role of nicotine in cardiac events, the Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use does not address nicotine specifically and only refers to cigarette use.

- g. Before prescribing a contraceptive, the pharmacist shall ensure that the patient is appropriately trained in the administration of the requested or recommended contraceptive medication.
- h. When a contraceptive is prescribed, the pharmacist must provide the patient with appropriate counseling and information for the product prescribed, as required by the statute and corresponding regulations. In addition to verbal counseling, the pharmacist must also supply a fact sheet to the patient that is specific to the drug prescribed. The information that must be provided includes the following:
  - i. the name and description of the drug;

- ii. the dosage form, dose, route of administration, and duration of drug therapy;
- iii. intended use of the drug and expected action;
- iv. directions and precautions for preparation, administration, and appropriate use by the patient;
- v. common severe side effects, adverse effects, or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
- vi. techniques for self-monitoring of drug therapy;
- vii. proper storage;
- viii. action to be taken in the event of a missed dose;
- ix. the importance of receiving recommended preventative health screenings and the need for medical follow-up;
- x. that self-administered hormonal contraception does not protect against sexually transmitted infections (STIs); and
- xi. any other information relevant to the patient's drug therapy.
- i. When a contraceptive is prescribed, the pharmacist must provide the patient with a written record of the contraceptive prescribed. The *Pharmacist Referral and Visit Summary* template provided below may be used for this purpose. At a minimum, the record must include:
  - i. the patient's name and date-of-birth;
  - ii. the name, practice address, and telephone number for the prescribing pharmacist;
  - iii. the date on which the prescription was issued;
  - iv. the name and strength of the contraceptive that was prescribed; and
  - v. the quantity prescribed and how many refills were authorized (if any)

#### **Pharmacy Technicians and Pharmacist Interns**

A pharmacist who is authorized to prescribe a hormonal contraceptive is permitted to, at the request of a trained prescribing pharmacist, assist the pharmacist in prescribing a hormonal contraceptive to a patient by providing screening documentation to the patient, taking and recording the patient's blood pressure and documenting the patient's medical history, if the pharmacy technician has completed an approved training course for prescribing of hormonal contraceptives. A registered pharmacist intern may prepare a prescription for a hormonal contraceptive under the direct supervision of a trained

prescribing pharmacist, but before the prescription is processed or dispensed, a pharmacist authorized to prescribe under this protocol must review, approve, and sign the prescription.

#### Prescription record.

The pharmacist shall use the Connecticut Hormonal Contraceptive Self-Screening Questionnaire completed by the patient as the record of the prescription.

- 1. Completed screening documents for hormonal contraceptives, and any other screening document as applicable, shall be maintained as the prescription on file at the pharmacy for the patient prescribed the hormonal contraceptive for at least three years.
- 2. Each prescription for hormonal contraceptive shall be transmitted to the electronic prescription drug monitoring program established pursuant to 21a-254(j) of the general statutes within twenty-four hours of dispensation.
- 3. All records created as part of a pharmacist prescribing a hormonal contraceptive shall be maintained for a minimum of three years.
- 4. All records created as part of a pharmacist prescribing hormonal contraceptives shall be readily retrievable and provided to the Department within forty-eight hours.

## **Connecticut Hormonal Contraceptive Self-Screening**

Patient N	NameHealth Care Provider's Name	Date_	
Date of I	NameHealth Care Provider's Name BirthAgeWeight		
Do you h	nave health insurance?   Yes   No		
When w	as the date of your last women's health clinical visit?		
	gies to Medications?   Yes  No If yes, list them here:		
Do yo	ou have a preferred method of birth control that you would like to use?		
□ Dai		(IUD, im	plant)
Backg	round Information:		
1	Do you think you might be pregnant now?	Yes □	No □
2	When was the first day of your last menstrual period?	/_	
3	Have you ever taken birth control pills, or used a birth control patch, ring, or injection?	Yes □	No □
	Have you previously had contraceptives prescribed to you by a pharmacist?	Yes 🗆	No □
	Did you ever experience a bad reaction to using hormonal birth control?	Yes 🗆	No □
	- If yes, what kind of reaction occurred?	<del> </del>	
	Are you currently using any method of birth control including pills, a birth control patch, ring or shot/injection?	Yes □	No □
	- If yes, which one do you use?		
4	Have you ever been told by a medical professional not to take hormones?	Yes 🗆	No □
5	Have you used emergency contraception within the last 5 days?	Yes□	No 🗆
		163 🗆	
	al History:		
6	Do you smoke cigarettes?	Yes 🗆	No 🗆
	- If yes, number of cigarettes per day:  Do you vape nicotine products, use a nicotine replacement or use other tobacco products?	Yes 🗆	_ /day No □
7	Have you had a recent change in vaginal bleeding that worries you?	Yes 🗆	No 🗆
8	Have you given birth within the past 21 days? If yes, how long ago?	Yes 🗆	No 🗆
9	Are you currently breastfeeding?	Yes 🗆	No 🗆
10	Do you have diabetes?	Yes 🗆	No 🗆
11	Do you get migraine headaches?	Yes 🗆	
11a	If so, have you ever had the kind of headaches that start with warning signs or symptoms, such	Yes 🗆	No 🗆
110	as flashes of light, blind spots, or tingling in your hand or face that comes and goes completely	165 🗆	No □
	away before the headache starts?		
12	Are you being treated for inflammatory bowel disease?	Yes □	No □
13	Do you have high blood pressure, hypertension, or high cholesterol? (Please indicate yes, even	Yes □	No □
	if it is controlled by medication.)		
14	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes □	No □
15	Have you ever had a blood clot?	Yes □	No □
16	Have you ever been told by a medical professional you are at risk of developing a blood clot?	Yes □	No □
17	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes □	No □
18	Will you be immobile for a long period of time? (e.g. flying on a long airplane trip, etc.)	Yes □	No □

19			
	Have you had bariatric surgery or stomach reduction surgery?	Yes □	No □
20	Do you have or have you ever had breast cancer?	Yes □	No □
21	Have you had a solid organ transplant?	Yes □	No □
22	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes 🗆	No □
23	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes □	No □
24	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?  - If yes, list them here:	Yes 🗆	No 🗆
25	Do you have any other medical problems or take any medications, including herbs or supplements?  - If yes, list them here:	Yes 🗆	No 🗆
26	I understand that if the pharmacist prescribes any medication for me that it is for the purpose of hormonal contraception.	Yes 🗆	No 🗆
Signat	ureDate_		
Drea	nancy Screen		
a. Di	d you have a baby less than 6 months ago, are you fully or nearly-fully breast feeding, AND have had no menstrual period since delivering your baby?	Yes 🗆	No 🗆
	ve you had a baby in the last 4 weeks?	Yes □	No 🗆
c. Did	d you have a miscarriage or abortion in the last 7 days?	Yes □	No 🗆
d. Di	d your last menstrual period start within the past 7 days?	Yes □	No 🗆
e. Ha	ve you abstained from sexual intercourse since your last menstrual period or delivery?	Yes □	No 🗆
1. Па	ve you been using a reliable contraceptive method consistently and correctly?  BP Reading/	Yes 🗆	No [
		<b>1</b> .	
R:	Note: RPH must refer patient if either systolic or diastolic reading is out of range, per algorithm		
Ŗ			
R			
R	Drug Prescribed Rx_		<u> </u>